



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2020-0347; FRL-8871-01-OCSP]

#### Propamocarb; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of propamocarb in or on Vegetable, *Brassica*, head and stem, group 5-16. The Interregional Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2020-0347, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to

provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Marietta Echeverria, Acting Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDFRNotices@epa.gov](mailto:RDFRNotices@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

#### *B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

#### *C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the

instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2020-0347 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2020-0347, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the *Federal Register* of September 10, 2020 (85 FR 55810) (FRL-10013-78), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3),

announcing the filing of a pesticide petition (PP 0E8832) by Interregional Project Number 4 (IR-4), Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.499 be amended by establishing a tolerance for residues of the fungicide propamocarb, (propyl *N*-[3-(dimethylamino)propyl]carbamate), in or on Vegetable, *Brassica*, head and stem, group 5-16 at 15 parts per million (ppm). That document referenced a summary of the petition prepared by IR-4, the petitioner, which is available in docket for this action, Docket ID EPA-HQ-OPP-2020-0347, at <https://www.regulations.gov>. Two comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCFA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCFA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCFA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCFA section 408(b)(2)(D), and the factors specified in FFDCFA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for propamocarb including

exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with propamocarb follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections of the rule that would repeat what has been previously published in tolerance rulemakings for the same pesticide chemical. Where scientific information concerning a particular pesticide chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings and republishing the same sections is unnecessary and duplicative. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a number of tolerance rulemakings for propamocarb, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to propamocarb and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

#### *A. Toxicological Profile*

For a summary of the Toxicological Profile of propamocarb, see Unit III.A. of the December 5, 2019 rulemaking (84 FR 66616) (FRL-10000-33).

#### *B. Toxicological Points of Departure/Levels of Concern*

For a summary of the Toxicological Points of Departure/Levels of Concern used for the risk assessment, see Unit III.B. of the February 7, 2017 rulemaking (82 FR 9519) (FRL-9957-68).

#### *C. Exposure Assessment*

Much of the exposure assessment remains the same, although the dietary exposure and risk assessments for propamocarb were updated. These updates are discussed in this

section; for a description of the rest of EPA's approach to and assumptions for the exposure assessment, see Unit III.C. of the December 5, 2019 rulemaking.

EPA's dietary exposure assessments have been updated to include the additional exposures for the new use of propamocarb on the commodities in crop group 5-16. The assessment used the same assumptions as the December 5, 2019 rule concerning tolerance-level residues, default and empirical processing factors and 100% crop treated (PCT) for all commodities in both the acute and chronic dietary exposure assessments.

*Drinking water, non-occupational, and cumulative exposures.* Drinking water and non-occupational exposures are not impacted by the new use, and thus have not changed since the last assessment. For a summary of the dietary exposures from drinking water, see Unit III.C.2. of the December 5, 2019 rulemaking. Propamocarb is registered for use on golf course turf resulting in potential residential post-application dermal exposure. During Registration Review, a dermal endpoint was not selected; therefore, a quantitative residential dermal exposure assessment was not necessary and was not conducted. EPA's conclusions concerning cumulative risk remain unchanged from Unit III.C.4. of the December 5, 2019 rulemaking.

*Safety factor for infants and children.* EPA continues to conclude that there is reliable data showing that the safety of infants and children would be adequately protected if the FQPA SF were reduced from 10X to 1X for all exposure scenarios. The reasons for that decision are articulated in Unit III.D in the December 5, 2019 rulemaking.

*Aggregate risks and Determination of safety.* EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute population adjusted dose (aPAD) and the chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of

departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD; they are 42% of the aPAD for all infants, the most highly exposed subpopulation. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 54% of the cPAD for females 13 to 49 years old, the most highly exposed subpopulation.

A short- and intermediate-term oral adverse effect was identified; however, propamocarb is not registered for any use patterns that would result in either short- or intermediate-term oral residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term oral residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short- or intermediate-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for propamocarb. Additionally, based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, propamocarb is not expected to pose a cancer risk to humans.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to propamocarb residues. More detailed information about the Agency's analysis can be found at <https://www.regulations.gov> in the document titled "Propamocarb Hydrochloride (HCl).

Human Health Risk Assessment for Proposed Uses in/on Vegetable, *Brassica*, Head and Stem, group 5-16” in docket ID number EPA-HQ-OPP-2020-0347.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

For a discussion of the available analytical enforcement method, see Unit IV.A. of the December 5, 2019 rulemaking.

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex MRLs for residues of propamocarb in/on cabbage, cauliflower, and broccoli are 3 ppm, 2 ppm, and 1 ppm, respectively. As these levels are significantly less than the recommended tolerance level of 15 ppm for Vegetable, *Brassica*, head and stem, group 5-16, harmonization is not possible because U.S. growers could have violative residues despite legal use of propamocarb according to the label.

##### *C. Response to Comments*

Two comments were submitted to the docket in response to the September 10, 2020 Notice of Filing. The first commenter stated that there need to be regulations for residues of pesticide chemicals in/on various commodities but expressed concern about

the increasing use of pesticides. The commenter urged EPA to fully evaluate the submitted data as soon as possible to protect the U.S. public. Another commenter expressed concerns regarding producers making products cheaper or using pesticides for economic gain without considering human health. The commenter stated that the government should have the ability to monitor the chemicals put into food.

The Agency appreciates these comments and believes that the laws applicable to pesticide tolerances address these concerns. Specifically, the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerance is safe. As explained in this rule and in the supporting human health risk assessment in docket ID number EPA-HQ-OPP-2020-0347, EPA makes this determination based on an analysis of the toxicology studies and then conducting detailed exposure and risk assessments. The Agency's thorough process considers the validity, completeness, and reliability of the available data as well as other factors required by the FFDCA. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticide>.

## **V. Conclusion**

Therefore, tolerances are established for residues of propamocarb, (propyl *N*-[3-(dimethylamino)propyl]carbamate), in or on Vegetable, *Brassica*, Head and Stem, Group 5-16 at 15 ppm.

## **VI. Statutory and Executive Order Reviews**

This action establishes a tolerance under FFDCA section 408(d) in response to petitions submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action

has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCa section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCa section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501

*et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

## **List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 8, 2021.

**Marietta Echeverria,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

**PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.499, amend table 1 to paragraph (a) by adding in alphabetical order the entry “Vegetable, *Brassica*, Head and Stem, Group 5-16” to read as follows:

**§ 180.499 Propamocarb; tolerances for residues.**

(a) \* \* \*

**Table 1 to Paragraph (a)**

Commodity	Parts per million
* * * *	* * *
Vegetable, <i>Brassica</i> , Head and Stem, Group 5-16	15
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